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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,306

06/20/2005

Michael O'Rourke

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,306	Applicant(s) O'ROURKE ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8-12, 18, 25, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Hegde et al. (US Pub. No. 2004/0147803). Hegde et al. discloses the following of the claimed invention: a method of treating a stiffened blood vessel to help it resume normal function, said method comprising at least substantially encasing a stiffened portion of said blood vessel (paragraphs 0067-0068, 0089-0091) with an elastic membrane formed of biocompatible material (paragraphs 0071, 0073) such that said membrane engages said stiffened portion of said blood vessel to thereby reduce the external diameter of said stiffened portion of said blood vessel (paragraph 0069).

Claims 2-4 are disclosed in paragraph 0067.

Hegde et al. discloses the following of claim 5: the method of claim 1 wherein said stiffened portion of said blood vessel is a grafted synthetic portion of said blood vessel (paragraph 0089).

Hegde et al. discloses claims 8-10 and 12 in Figures 2-4, 7, and 10-13; paragraphs 0078-0079.

Hegde et al. discloses the following of claim 11: the method of claim 8 wherein the opposing end portions of said membrane sheet are secured by suturing (paragraph 0088).

Hegde et al. discloses claim 25 is paragraph 0071.

Hegde et al. discloses claim 28 is paragraphs 0089-0091.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hegde et al. in view of Chuter (US Pat. No. 5,387,235). Hegde et al. discloses the invention substantially as claimed, however, Hegde et al. does not disclose constructing the graft woven polyester. Chuter teaches a stent with a woven polyester graft in col. 9, lines 12-43 for the purpose of utilizing the material's elasticity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the graft from woven polyester in order to utilize the material's elasticity.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hegde et al. in view of Von Oepen (US Pub. No. 2002/0151959). Hegde et al. discloses the invention substantially as claimed, however, Hegde et al. does not disclose dilating the vessel prior to treatment. Von Oepen teaches a stent where the vessel is dilated prior to treatment in paragraphs 0001-0002 for the purpose of preventing the vessel from closing. Therefore, it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to dilate the vessel prior to treatment in order to prevent the vessel from closing.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hegde et al. in view of Spaulding (US Pat. No. 5,304,200). Hegde et al. discloses the invention substantially as claimed, however, Hegde et al. does not disclose welding the ends of the prosthesis. Spaulding teaches a stent with welded ends in col. 5, lines 13-49 for the purpose of securing the prosthesis in its desired shape. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to weld the ends of the prosthesis in order to secure the prosthesis in its desired shape.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hegde et al. in view of Picha (US Pat. No. 5,057,118). Hegde et al. discloses the invention substantially as claimed, however, Hegde et al. does not disclose connecting the ends of the prosthesis with interlocking structures. Picha teaches an occlusion device with interlocking ends in col. 3, lines 1-39 for the purpose of securing the prosthesis in its desired shape. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to connect the ends of the prosthesis with interlocking structures in order to secure the prosthesis in its desired shape.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hegde et al. in view of Jones (US Pat. No. 4,202,349). Hegde et al. discloses the invention substantially as claimed, however, Hegde et al. does not disclose markings on the prosthesis. Jones teaches a stent with markings in col. 2, line 52 through col. 3, line 16 for the purpose of helping the physician to properly locate the prosthesis. Therefore, it would have been obvious to one of

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ordinary skill in the art at the time the invention was made to place markings on the prosthesis in order to help the physician to properly locate the prosthesis.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hegde et al. in view of Dusbabek et al. (US Pub. No. 2001/0007082). Hegde et al. discloses the invention substantially as claimed, however, Hegde et al. does not disclose how the sheet membrane is formed. Dusbabek et al. teaches a stent where a cylinder is cut to form different structures to be used with the prosthesis in paragraphs 0074-0076 for the purpose of allowing the user to create the desired shape for the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a cut cylinder to form different structures to be used with the prosthesis in order to allow the user to create the desired shape for the prosthesis.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hegde et al. in view of Fontaine (US Pat. No. 5,314,472). Hegde et al. discloses the invention substantially as claimed, however, Hegde et al. does not disclose the prosthesis having a spiral shape. Fontaine teaches a stent with a spiral shape in col. 2, line 50 through col. 3, line 7 for the purpose of allowing the prosthesis to properly fit to its desired location. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the prosthesis with a spiral shape in order to allow the prosthesis to properly fit to its desired location.

In addition, it would have been an obvious matter of design choice to give the prosthesis a spiral shape, since such a modification would have involved a mere change in the shape of the

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component. A change in shape is generally recognized as being within the level of ordinary skill in the art.

Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hegde et al. Hegde et al. discloses the invention substantially as claimed except for the specific properties of size, and stiffness claimed by the Applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthesis with the claimed physical characteristics, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hegde et al. in view of Silverstrini et al. (US Pat. No. 4,834,755). Hegde et al. discloses the invention substantially as claimed, however, Hegde et al. does not disclose the using elastic polyurethane in the prosthesis. Silverstrini et al. teaches a biological prosthesis using elastic polyurethane in columns 5 and 6 for the purpose of utilizing the material's biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use elastic polyurethane in the prosthesis in order to utilize the material's biocompatibility.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Schillinger/
Examiner, Art Unit 3774

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738